Schedule of Accreditation



Organisation Name Mater Private Hospital Trading As INAB Reg No 191MT Fiona O'Brien Contact Name Address Blood Transfusion Department, Eccles Street, Dublin, D7 **Contact Phone No** 01-8858346 Fiona.OBrien@materprivate.ie Email Website Accreditation Standard EN ISO 15189 Standard Version 2012 Date of award of accreditation 22/04/2008 Scope Classification Microbiology and virology **Scope Classification Blood Transfusion Science** Scope Classification Haematology **Scope Classification** Immunology Scope Classification Histopathology and cytopathology Scope Classification Chemical pathology Services available to the public¹

¹ Refer to document on interpreting INAB Scopes of Accreditation

	Sites from which accredited services are delivered							
	(the detail of the accredited services delivered at each site are on the Scope of Accreditation)							
	Name	Address						
1	1 Head Office Blood Transfusion Department, Eccles Street, Dublin, D7							

Scope of Accreditation

Head Office

Blood Transfusion Science

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non- CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO Rh D Blood Grouping	Red Cells & Plasma	1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0002 LS-BT-0041
1020 Transfusion science - .03 Blood group antibody screen	Antibody Screening	Plasma/Serum	1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0002 LS-BT-0041
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody Identification		1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0010
1020 Transfusion science - .05 Cross match compatible donor units	Compatibility Testing	Red Cells & Plasma	1. Manual 2. Electronic Issue	1. Manual 2. Electronic Issue	N/A	LM-BT-0007 LS-BT-0047
1020 Transfusion science - .06 Red cell phenotyping	Antigen Typing	Red Cells	1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0014
1020 Transfusion science - .99 Miscellaneous tests	Direct Coombs		1. Manual 2. IH500	Automated & Manual	N/A	LM-BT-0020

a The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

Chemical Pathology

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non- CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Albumin	Serum	Bromocresol green	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Alk Phos	Serum	Roche AMP Buffer	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	ALT	Serum	Tris buffer without p5p		CE based on standard method	LM-BIO-0014
	Amylase	Serum/Urine	Roche liquid stable pnpg7		CE based on standard method	LM-BIO-0014
	AST	Serum	Tris buffer without p5p		CE based on standard method	LM-BIO-0014
	Bicarbonate		Enzymatic		CE based on standard method	LM-BIO-0014
	Calcium	Serum/Urine	NM-BAPTA		CE based on standard method	LM-BIO-0014
	Calcium corrected	Serum	Calculation		CE based on standard method	LM-BIO-0014
	Chloride	Serum / urine	ISE indirect		CE based on standard method	LM-BIO-0014
	Cholesterol HDL	Serum	Direct HDL		CE based on standard method	LM-BIO-0014
	Cholesterol LDL		Direct LDL		CE based on standard method	LM-BIO-0014

Cholesterol Total	Serum	Cholesterol oxidase	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
СК	Serum	CK-NAC(IFCC)	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Creatinine /creatinine clearance serum / urine	Serum / urine	Roche Creatinine Enzymatic	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
CRP	Serum	Immunoturbidimetric	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Digoxin		Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
eGFR	Serum/Urine	Calculation	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Gamma GT	Serum	Gamma glut3carb4nitro	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Globulin		Calculation	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Glucose	Serum/Plasma/CSF/Urine	Hexokinase	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Iron	Serum	FerroZine without deproteinization	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
LDH	Serum	L to P IFCC	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Magnesium	Serum	Xylidyl blue	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
NT-PRO-BNP		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Phosphate		Phosphomolybdate UV	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Potassium	Serum / urine	Indirect ISE	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Sodium	1	Indirect ISE	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Total Bilirubin	Serum	Dichlorophenyl Diazonium	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
Triglyceride	Serum	Lipase	Roche Cobas 6000	CE based on standard method	LM-BIO-0014

	Urate	Serum	Uricase	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Urea	Serum / urine	Urease	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	hs-Troponin T	Serum	ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Total Protein	Serum/Urine/CSF	ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
1061 Clinical Chemistry - .06 Blood pH and gas tensions	HbA1c	Whole Blood	HPLC	Adams Arkray 8160		LS-BIO-0029 Operation of the Arkray A1C HA-8160 Analyser System LM-BIO-0012 Determination of HBA1C in a Patient Sample
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Gentamicin	Serum	EIA	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Vanc		KIMS	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
1061 Clinical Chemistry - .20 Hormones	Beta hCG		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Cortisol		Immunoassay	Roche Cobas 6000	CE marked	LM-BIO-0014
	Free T4		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	PTH		Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO_0024
	TSH		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
1061 Clinical Chemistry - .40 Iron studies	Ferritin		ECLIA	Roche Cobad 6000	CE	LM-BIO-0014
	Transferrin		Immunoturbidimetric	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Transferrin Saturation		Calculation	Roche Cobas 6000	CE based on standard method	LM-BIO-0014

1061 Clinical Chemistry - .45 Vitamin B12 and folate	B12		ECLIA	Roche Cobas 6000	CE	LM-BIO-0014
	Folate		ECLIA	Roche Cobas 6000	CE	LM-BIO-0014
1061 Clinical Chemistry - .47 Vitamin assays	Vitamin D	Serun	Immunoassay	Roche Cobas 6000	CE	LM-BIO-0014
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	Ca125	Serum	ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	Ca153		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	CEA		ECLIA Immunoassay	Roche Cobas 6000	CE based on standard method	LM-BIO-0014
	TPSA		ECLIA Immunoassay		CE based on standard method	LM-BIO-0014
1061 Clinical Chemistry - .60 Glycohaemoglobins	HbA1c	Whole Blood	HPLC	Adams Arkray 8160V	CE based on standard method	LM-BIO-0012 Determination of HBA1C in a Patient Sample

Haematology

Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non- CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology01 Blood counts	Automated Full Blood Counts	Whole Blood	Fluorescence Flow Cytometry Method (FCM) – a semiconductor laser (639nm). Hydrodynamic Focussing DC detection – RBC and PLT analysis. • SLS Haemoglobin Method – cyanide- free HGB analysis.	Automated using Sysmex XN 2000	CE Marked	LS-HAEM-0042
1030 Haematology02 Visual examination of blood films	Visual examination of blood films		Modified Wrights Stain	Hematek		LM-HAEM-0028 Preparation, Microscopic Examination & Reporting of Blood Films LM-HAEM-0043 Staining of Blood Films using the Hematek Staining Machine LS-HAEM-0016 The Handling of Specimens in the Haematology Department

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1030 Haematology03 Erthrocyte sedimentation rate	Erythrocyte Sedimentation Rate		The surface layer of the erythrocytes is detected by means of a change of light intensity at the beginning of the measuring process and after one hour	Desaga S2000		LM-HAEM-0042 ESR Determination using the Desaga S2000 & Sedivette Back-up LS-HAEM-0016 The Handling of Specimens in the Haematology Department
1030 Haematology06 Automated reticulocyte counts	Automated Reticulocyte Counts			Automated using Sysmex XN 2000		LS-HAEM-0042 OPERATION, FBC AND RETICULOCYTE ANALYSIS USING SYSMEX XN-2000
1030 Haematology30 Tests for haemoglobin variants and thalassaemia	Sickle Cell Screen		Haemoglobin solubility test method	Manual macroscopic visualisation		LM-HAEM-0022 Sickle Cell Disease and Sickle Cell Trait Screening LS-HAEM-0016 The Handling of Specimens in the Haematology Department LS-HAEM-0020 Operation & Maintenance of MPW- 223e Centrifuge, Stuart Waterbath, Angelantoni Fridge
1030 Haematology41 General haemostasis related tests	General Haemostasis tests inclduging PT, INR, APTT, Fibrinogen quantation, D-dimer, correction studies	Plasma	Mechanical clotting system	Stago compact Max	CE	LM-HAEM-0046

Histopathology and Cytopathology

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non- CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1051 Histopathology01 Processing fixed specimens for Histopathological testing	Automated Embedding	Human Tissue		Based on Standard Method	N/A	LS-HIST-0064 Operation of the Tissue Tek A120 Auto Embedder
	Automated Haematoxylin			ST and Leica Coverslipper CV Chemflow Fume Cabinet	CE/Based on standard method.	Automated Haematoxylin and Eosin Staining LM-HIST-0009 Staining LM-HIST-0010 Stains & Solutions LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0037 Disposal of Chemical and Clinical Waste
			Leica Spectra ST Staining & Spectra CV Coverslipper		CE/Based on standard method.	TBC
	Cover slipping & sorting		Automated coverslipping of slides using Leica Multistainer ST and Leica CV. Manual		CE/Based on standard method.	Coverslipping and Sorting LM-HIST-0011 Coverslipping in Histology & Cytology

	checking and labelling and distribution of slides.			LS-HIST-0010 Operation of the Nikon Microscope LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0024 Labeling, Sorting and Checking Slides and Recording Numbers LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV
Coverslipping and Sorting	Automated coverslipping of slides using Leica Spectra ST and Leica Spectra CV. Manual checking, labelling and distribution of slides.		CE/Based on standard method.	TBC
Cut up		AFOS Cut Up Room Balances- Ohous, Denver		LM-HIST-0022 Principles of good practice and training manual for Medical Scientists involved in Cut Up LS-HIST-0016 Operation of Balances in Histology LS-HIST-0044 AFOS Cut Up Room LS-HIST-0050 Operation of the G2speech
Embedding	impregnating Human			LM-HIST-0007 Embedding LS-HIST-0039 Operation of Para Trimmer LS-HIST-0045 Operation of Tissue

	create a wax tissue block.			Tek TEC 5 Embedding Centre
Microtomy		Leica RM 2255 (1- 4) RA Lamb Waterbaths Histology Ovens	CE/Based on standard method.	Manual and motorized sectioning of processed tissue LM-HIST-0008 Cutting of Paraffin Blocks LS-HIST-0004 Operation of the Microtomes LS-HIST-0006 RA Lamb Waterbaths LS-HIST-0014 Operation of the Histology Ovens
Specimen Reception Automated and Manual Haematoxylin and Eosin Staining Coverslipping	Manual labelling and entering specimens onto LIS. Automated printing of cassettes using the Leica IPC Automated Cassette	Leica IPC Automated Cassette Printer	CE/Based on standard method.	LS-LIS-0004 Operation of the Clinisys Laboratory Information Management System in Histology LM-HIST-0001 Specimen Reception, Labeling & Charging LM-HIST-0004 Fixation & Decalcification LS-HIST-0055 Operation of the Leica IPC Automated Cassette Printer
Tissue processing	Automated method of xylene, alcohol, paraffin wax infiltration of Human tissue samples usinf the VIP Tissue Processor/ Leica ASP6025	VIP Tissue Processor Leica ASP6025 Tissue Processor	Based on standard method	LM-HIST-0006 Tissue Processing LS-HIST-0032 Operation of VIP Tissue Processor LS-HIST-0054 Operation of the Leica ASP6025

1051 Histopathology02 Processing fresh specimens for frozen section examination	Cut-up Frozen section cryotomy and staining	cutting of fresh tissue sample in AFOS cut up room. Manual use of Leica Cryostat to section tissue. Manual staining and coverslipping and labelling of slides.	Spectra and Leica	Based on standard method	Cryotomy and Staining LM-HIST-0002 Frozen Sections LM-HIST-0009 Staining LM-HIST- 0011Coverslipping in Histology & Cytology LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV LS-HIST-0009 Operation of the Leica Cryostat CM1950 LS-HIST-0044 AFOS Cut Up Room LS-HIST-0016 Operation of the Balances in Histology LS-HIST-0017 Operation of the Chemflow Fume Cabinet LS-HIST-0055 Operation of the Leica IPC Automated Cassette Printer
	Specimen Reception	Manual accepting, labelling and entering of specimens onto the LIS system.	N/A	N/A	LM-HIST-0001 Reception, Labeling & Charging
1051 Histopathology03 Histochemistry	Alcian Blue	special stain slides.		Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

	special' and coverslipping using Leica Multistainer ST5020 and Leica Coverslipper CV5030. Manual checking labelling and sorting of slides.	Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver		
Alcian Blue/PAS	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Congo Red (Amyloid)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Diastase - PAS	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Gram	Manual staining of special stain slides. Automated 'finishing special' and	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

	coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Chemflow Fume Cabinet Balances- Ohous, Denver		
Millers Elastic	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Periodic Acid Schiffs (PAS)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Perls Prussian Blue	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV5. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010 Stains & Solutions, LM-HIST-0011 Coverslipping in Histology & Cytology, LS-HIST-0016 Operation of the Balances in Histology LS-HIST-0010 Operation of the Nikon Microscope, LS-HIST- 0017 Operation of the Chemflow Fume Cabinet, LS-HIST-0024 Labeling, Sorting and Checking Slides and

				Recording Numbers, LS-HIST-0049 Operation of the Leica Histocore Spectra ST and CV
Reticulin (Gordon & Sweets)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Shikata Orcein	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
Special stains	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper CV5. Manual checking labelling and sorting of slides.	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	CE/Non-CE/Based on standard method	LM-HIST-0009 Staining
Trichrome (Gomoris)	Manual staining of special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST and Leica Coverslipper	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049

			CV. Manual checking labelling and sorting of slides.	Balances- Ohous, Denver		
	Trichrome (Masson)		special stain slides. Automated 'finishing special' and coverslipping using Leica Multistainer ST	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
	Van Gieson		special stain slides. Automated 'finishing special' and	Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
	Ziehl Neelsen (ZN)			Nikon Microscope Leica Multistainer ST and Leica Coverslipper CV Chemflow Fume Cabinet Balances- Ohous, Denver	Based on standard method	LM-HIST-0010, 0011, 0016, 0010, 0017, 0024, 0049
1051 Histopathology09 Immunohistochemistry	Actin	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Actin SM		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

				the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE		LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

AE1AE3
BCL2
BCL6

BEREP4

Ca 125

Calponin

Calretinin

					the Leica Bond III in Histology
CAM5.2(Cyto8/18)	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD 20 (L26)	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD10	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD117 (c-kit)	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD138	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD15 (Leu M1)	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD23	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD3	Immunc	ostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

				the Leica Bond III in Histology
CD30 (Ki1)	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD34	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD4	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD45 (CLA)	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD5	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD68 (KP1)	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD79a	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CD8	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

				the Leica Bond III in Histology
CDX2	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
CEA	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Chromogranin	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Cyclin D1	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Cyt 903(HMWCK)	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Cyto 20	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Cyto 5/6	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Cyto 7	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

				the Leica Bond III in Histology
D240	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Desmin	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Dual Ck903/racemase	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Dual Napsin /TTF1	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
E-Cadherin	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
EMA	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
ER	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
GATA3	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with

					the Leica Bond III in Histology
H. pylori (HLO)		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
HMB45		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Immunohistochemistry staining methods	Human tissue	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and Coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking an sorting of slides.	Nikon Microscope Chemflow Fume Cabinet	CE/Based on standard method.	LM-HIST-0011 Coverslipping in Histology & Cytology
Карра	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Lambda		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
Melan A	Human tissue	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV.Chemflow Fume Cabinet. Manual checking and sorting of	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

		Manual checking an sorting of slides.	slides. Nikon Microscope		
MLH1	Histology	Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
MSH2		Immunostainer	CE	N/A	LS-HIST-048 Operation of and Immunostaining with the Leica Bond III in Histology
MUM1	Human tissue	Immunostainer	CE	N/A	LS-HIST-0010, 0017, 0024, 0048, 0049
Napsin A		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST5020 and Leica Coverslipper CV5030. Manual checking an sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST5020 and Leica Coverslipper CV5030.Chemflow Fume Cabinet. Manual checking an sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
P16		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
P53		Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV.	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

	slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking an sorting of slides.	Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope		
PR	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV.Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
PSA	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
PSMA	Immunostainer	CE	N/A	LS-HIST-0010, 0017, 0024, 0048, 0049
Racemase		Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV.Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
S-100	Automated staining of immuno slides using the Leica Bond III.	Leica Bond III Immunostainer Leica Multistainer	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

	Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope		
SMMS	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST5020 and Leica Coverslipper CV5030. Manual checking an sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST5020 and Leica Coverslipper CV5030.Chemflow Fume Cabinet. Manual checking an sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
Synaptophysin	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
TTF1	Automated staining of immuno slides using the Leica Bond III. Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	Leica Bond III Immunostainer Leica Multistainer ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049
Vimentin WT1	Automated staining of immuno slides using the Leica Bond III.	Leica Bond III Immunostainer Leica Multistainer	CE/Based on standard method.	LS-HIST-0010, 0017, 0024, 0048, 0049

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			Automated Finishing and coverslipping of slides using Leica Multistainer ST and Leica Coverslipper CV. Manual checking and sorting of slides.	ST and Leica Coverslipper CV. Chemflow Fume Cabinet. Manual checking and sorting of slides. Nikon Microscope		
1052 Cytopathology02 Non gynaecological cytology	Non gynaecological cytology, including Smears, Cytospin Preps and Cell Blocks, Automated Staining Papanicolaou and Manual Staining MGG	Human Tissue or Fluid	Cytospin Thin Prep2000, Leica Spectra ST & CV, Chemflow Fume Cabinet	CE	CE/Based on standard method.	TBC
	Non gynaecological cytology, including Smears Cytospin preps and Cell Blocks Automated Staining Papanicolaou Manual Staining MGG		Cytospin ThinPrep2000 Leica Multistainer ST5020 and Leica Coverslipper CV5030 Chemflow Fume Cabinet	CE		LM-CYT-002 Specimen Preparation and Fixation LM-CYT-004 Cytology Staining Methods LM-HIST-0011 Coverslipping in Histology & Cytology LS-HIST-0024 Labeling, Sorting and Checking Slides & Recording Numbers

Immunology

Medical pathology field - Test	Test/Assay	Specimen Type	Equipment/Technique	Method (CE/Non- CE/In house developed/based on standard method)	Range of measurement	Std. Ref & SOP
1040 Immunology01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids	IgA, IgG, IgM	Serum	Immunoturbidimetric	Optilite Special Protein Analyser	CE Marked	LM-IMM-0019 Individual Tests Performed on the Optilite Optimised Protein SystemI
1040 Immunology02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Serum Electrophoresis Immunofixation	Serum & Urine	Agarose Gel	Hydrasys 2 Scan	CE Marked	LM-IMM-0008 Electrophoresis of Serum and Urines LM-IMM-0012 Immunofixation of Serum and Urine LS-IMM-0013 Operation of the Hydrasys 2
1040 Immunology14 b2- microglobulin	Beta 2 microglobulin	Serum	Immunoturbidimetric	Optilite Special Protein Analyser	CE marked	LM-IMM-0019 Individual Tests Performed on the Optilite Optimised Protein SystemI
1040 Immunology99 Miscellaneous tests	Kappa free light chains		Immunoturbidimetric	Optilite Special Protein Analyser	CE marked	LM-IMM-0019 Individual Tests Performed on the Optilite Optimised Protein SystemI
	Lambda free light chains		Immunoturbidimetric	Optilite Special Protein Analyser	CE marked	LM-IMM-0019 Individual Tests Performed on the Optilite Optimised Protein SystemI

INAB Registration No. 191MT

Microbiology and Virology

Medical pathology field - Test	Test/assay	Specimen Type	Equipment/Technique	Method (CE/Non- CE/In house developed/based on standard method)	Range of measurement	Std. ref & SOP
1011 Macroscopic examination and description	Examination of faecal, sputa samples	Faeces, sputum	Visual assessment	None	Based on standard method	LM-MICRO-0067 Investigation of Faeces Samples LM-MICRO-0066 Investigation of Sputum, Bronchial Washings and associated specimens
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Cell count for body fluids	Body fluids, CSF	Microscopy: cell count	Nikon microscope	Based on standard method	LM-MICRO-0019 Investigation of CSF
	Examination of urine samples	Urine	Microscopy: cell count	Nikon microscope	Based on standard method	LM-MICRO-0022 Investigation of Urine
	Gram stain	Body fluids, pus, CSF, HVS, Eye	Microscopy	Nikon microscope	Based on standard method	LM-MICRO-0031 Performing a Gram Stain
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring	Isolation of significant pathogens in clinical samples	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/	Culture	PolEko Incubator Euroclone CO2 Incubator Oxoid atmospheric generation system	Based on standard method	LM-MICRO-0034, 0023, 0019, 0022, 0063, 0064, 0065, 0067

for growth01 Culture of general bacteria		throat/ mouth swabs, wound swabs, tips, drains, urine, stool.				
		Sputum, Bronchial washing	Culture	PolEko Incubator Euroclone CO2 Incubator	Based on standard method	LM-MICRO-0066 Investigation of Sputum, Bronchial Washings and associated specimens
	Screening for MRSA, CRE, VRE	Nose, throat, groin, rectal swabs	Culture	PolEko Incubator	Based on standard method CE marked chromogenic media	LM-MICRO-0034 Investigation of Screening Specimens LM-MICRO-0023 Inoculation of Culture Media LM-MICRO-0019 Investigation of CSF LM-MICRO-0022 Investigation of Urine LM-MICRO-0063 Investigation of ENT Specimens LM-MICRO-0064 Investigation of Sterile Fluids LM-MICRO-0065 Investigation of Swabs, Tissue, IV Cannulae and associated specimens LM-MICRO-0067 Investigation of Faeces Samples
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth02 Culture of fungi	Inoculation and incubation of plates	Bronchial washing, Sputa, Wound Swab, Tissue, Sterile Fluid, CSF, Ear Swab, Eye Swab, Tip	Culture	PolEko Incubator Memmert Incubator	Based on standard method	LM-MICRO-0036 Investigation of Fungal Specimens
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and	Anti HCV	Serum	Immunoassay	Roche Cobas 6000	CE marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001

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appropriate techniques - .03 Enzyme immunoassay,						Individual Tests Performed on the Roche Cobas Analyser
	Anti-HAV IgM		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
	Anti-HAV Total		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
	Anti-HBc		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
	Anti-HBs		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
	HBsAg		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the

						Roche Cobas Analyser
	HIV		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
	Syphillus TP		Immunoassay	Roche Cobas 6000	CE Marked	LS-SERO-0001 Operation of the Roche Cobas LM-SERO-0001 Individual Tests Performed on the Roche Cobas Analyser
		Nasopharyneal & Naospharyneal Aspirate	GeneXpert	PCR	N/A	LM-MICRO-0076
	identification systems for bacteria Use of Vitek 2 Compact	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/ throat/ mouth swabs, wound swabs, tips, drains, urine, stool.	Culture and sensitivity, biochemical tests, commercial identification systems, automated sensitivity testing, manual sensitivity testing.	Vitek 2 Compact	CE Marked	LM-MICRO-0058 The Oxidase Test LM-MICRO-0054 Campylobacter Identification LM-MICRO-0059 The Catalase Test LM-MICRO-0046 API Identification System LM-MICRO-0048 Isolate Identification using the RapID System LM-MICRO-0061 Use of Vitek Identification and Antimicrobial Susceptibility Testing

						Cards LM-MICRO-0060 Use of Shigella Polyvalent Agglutinating Sera LM-MICRO-0045 Use of the Streptex Kit and the PYR Test LM-MICRO-0056 Staphylococcus aureus Identification using the Staphaurex Plus Kit LM-MICRO-0050 The Wellcolex Colour Salmonella Kit LM-MICRO-0052 The E.coli O157 Test
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes)01 Anaerobes	Determination of MIC		MIC Strip	PolEko Incubator Euroclone CO2 Incubator	CE Marked	LM-MICRO-0027 Susceptibility Testing
		MIC	MIC Strip	Oxoid Atmosphere Generation system	CE Marked	LM-MICRO-0027 Susceptibility Testing
	Disc diffusion sensitivity testing		EUCAST disc diffusion	PolEko Incubator Euroclone CO2 Incubator	Based on standard method	LM-MICRO-0027 Susceptibility Testing
	Use of the Vitek 2 Compact	Fluids, CSF, pus, tissue, bone, HVS, Endocervical swab, penile/ urethral swab, IUCD, Ear/ eye/ nose/ throat/ mouth swabs, wound swabs, tips, drains, urine, stool.	Automated sensitivity testing	Vitek 2 compact	CE Marked	LM-MICRO-0027 Susceptibility Testing
			Automated sensitivity testing	Vitek 2 compact	CE Marked	LM-MICRO-0027 Susceptibility Testing

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